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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,344	11/03/2003	Andrew L. Cote SR.	1600/163	5277

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BROMBERG & SUNSTEIN LLP  
125 SUMMER STREET  
BOSTON, MA 02110-1618

EXAMINER
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MACNEILL, ELIZABETH

ART UNIT	PAPER NUMBER
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3767

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/13/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/700,344

Applicant(s)

COTE ET AL

Examiner

Elizabeth R. MacNeill

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,4-7,10-13,16-24,74 and 77-92 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-7,10-13,16-24,74 and 77-92 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 1/16/07.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 16 January 2007 has been entered.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1,4-7,10-13,16-24,74, and 77-92 are rejected under 35 U.S.C. 102(b) as being anticipated by CLOYD (US #3,806,086).

Regarding claim 1, Cloyd teaches a housing (10), having an inlet (9) and outlet (8); a plug member (14); a flexible gland member (18) wherein the gland member has a seal section (Fig 2, inlet portion), being aligned with the exterior inlet face of the housing to provide a swabbable surface (See Fig 2); wherein the plug

member comprises a cannula (92, 94) that defines a channel (25) for directing fluid through the valve (See Fig 2)

Regarding claims 4-7, 18-21, 77, 78, and 83-86 the plug member is moveable between an open and closed position, which prevents fluid flow when the valve is closed by occluding the passageway, and allows fluid flow when the passage is open (unoccluded) (See Fig 2 and Fig 3)

Regarding claims 10, 22, 79, and 87 the plug member is rigid (Col 2 line 26)

Regarding claims 11, 23, 80, 88 and 91 the plug member's longitudinal axis is parallel to the direction of the motion of the plug (Fig 2 and 3)

Regarding claim 12, 81, 89 and 92 the plug member is substantially within the gland member (Fig 2)

Regarding claim 13, Cloyd teaches a housing (10), having an inlet (9) and outlet (8); a plug member (14); a flexible gland member (18) wherein the gland member has a seal section (Fig 2, inlet portion), being aligned with the exterior inlet face of the housing to provide a swabbable surface (See Fig 2); wherein the plug member is capable of telescopically moving relative to the gland member. (See Fig 2 and 3). Examiner takes "telescopically moving" to mean slideably, which can be seen in the construction of the plug member relative to the gland member.

Regarding claims 16 and 75, the plug member defines a channel (25) for directing fluid through the valve.

Regarding claim 17, the plug member is a cannula (25).

Regarding claim 24, the gland member is secured to the housing and supports the plug member within the housing (Fig 2)

Regarding claim 74, Cloyd teaches a housing (10), having an inlet (9) and outlet (8); a plug member (14) moveably mounted within the passageway, wherein the plug member is movable between an open and closed position (Fig 2 and 3), and plug member being a cannula (25); a flexible gland member (18) wherein the gland member is secured to the housing and supports the plug member within the housing (Fig 2), and the gland occludes the opening (Fig 2), the gland member has a seal section (Fig 2, inlet portion), being aligned with the exterior inlet face of the housing to provide a swabbable surface (See Fig 2)

Regarding claim 82, Cloyd teaches a housing (10), having an inlet (9) and outlet (8); a rigid plug member (14) moveably mounted within the passageway; a flexible gland member (18) wherein the gland member is secured to the housing and supports the plug member within the housing (Fig 2) and the gland member has a seal section (Fig 2, inlet portion), being aligned with the exterior inlet face of the housing to provide a swabbable surface (See Fig 2); wherein the plug member defines a channel (25) for directing fluid through the valve.

Regarding claim 90, Cloyd teaches a housing (10), having an inlet (9) and outlet (8); a rigid plug member (14) moveably mounted within the passageway; a flexible gland member (18) wherein the gland member is secured to the housing and supports the plug member within the housing (Fig 2) and the gland member has a seal section (Fig 2, inlet portion), being aligned with the exterior inlet face

of the housing to provide a swabbable surface (See Fig 2); wherein the plug member is movable between an open and closed position (Fig 2 and 3); providing a portion of unoccluded fluid path through the valve.

### ***Response to Arguments***

3. Applicant's arguments filed 16 January 2007 have been fully considered but they are not persuasive. Regarding Cloyd as applied to claims 1,4-7,10-13,16-24,74, and 77-92, applicant has argued that Cloyd does not disclose a "medical valve with a seal section that is substantially aligned with the exterior inlet face." In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the *seal member being swabbable*) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The applicant has claimed that (1) the seal section is substantially aligned with the exterior inlet face and (2) that when the valve is closed, a swabbable surface is provided. The first limitation is met as shown in Figure 2, where the seal section is aligned axially with the inlet face (the inlet face is a flat disc, and the seal section is found along the center line of the disc). The applicant has not claimed an axis or dimensional relationship regarding the desired alignment between the inlet face and the seal. Therefore, any "alignment" will meet the claim language. Regarding the second limitation, the language of the claim does not require that the seal member is

swabbable, rather only that *any surface* is provided when the valve is closed which can be swabbed. Clearly, the exterior inlet face, and the entire body of the face can be swabbed in Fig 2. Therefore, Cloyd meets the claimed limitations and the USC 102 (b) rejection is maintained.

### **Conclusion**

4. This is a continued examination of the application. All claims are drawn to the same invention claimed in the earlier prosecution and have been finally rejected on the grounds and art of record in the previous Office. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 7:00-3:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM

*ERM*  
*2/6/07*

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

*Kevin C. Sirmons*